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10/589,335

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Carlo Pompei

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EXAMINER

HEGGESTAD, HELEN F

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,335	<b>Applicant(s)</b> POMPEI ET AL.	
	<b>Examiner</b> Helen F. Pratt	<b>Art Unit</b> 1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

**The finality of the last office action has been withdrawn in favor of the action below as required by the Pre-Appeal Brief Conference.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 34, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33, 34 and 35 are indefinite in that the product is to various forms of the product produced by the process of claim 1. However, as no amounts or degrees of concentration are found in claim 1, it is not seen that the process of claim 1 would have produced such products.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1789

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1- 5, 10-13, 28, 29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterson et al. (EP 0137671) or Lawhon et al. (EP 0174594) in view of Bishop, Chu et al. (US 2003/0064144 or 7,108,887). Winterson et al. disclose a process of making a fruit juice by separating the juice into pulp and liquid portions, and ultrafiltrating (UF) the liquid portion, which is then freeze concentrated. The pulp to be recombined is pasteurized (abstract and page 2, lines 19-30). Lawhon discloses that juice was obtained by squeezing the oranges, and separating the pulp using screening, sieving or centrifugation (page 7, lines 9-21). The juice was ultrafiltered, and the microorganisms in the retentate (pulp) were inactivated, and then recombined with the UF permeate (juice). The UF permeate was first treated to reverse osmosis before recombining the retentate with the permeate (abstract).

Claims 1, 2 and 3 differ from the references in washing the pulp. However, Chu et al. disclose a process of separating the pulp from citrus juice, washing the pulp (para. 13, and 14, entire paragraphs, lines 38-50 under Summary of the Invention, and Ex. 3. ). The juice and pulp are recombined. It would have been obvious to wash using an acidic solution since as above the protein has been removed from the serum by ultrafiltration. Claim 1 does not state what is removed from the pulp in order to make an hypoallergenic pulp. It is common to acidify wash solutions in order to reduce bacteria, which would have been within the skill of the ordinary worker, absent anything new or unobvious. Therefore, it would have been obvious to wash a

Art Unit: 1789

pulp as disclosed by Chu et al. , and to acidify the wash solution to reduce the level of bacteria, and then to recombine the pulp with the ultrafiltrated juice in the process of Winterson et al. or Lawhon et al. to provide a reconstituted product.

Claim 1 further requires ultrafiltering to reduce the Lipid Transfer Protein. As the process has been shown, it is seen that the LTP in the serum has been reduced. This washing of the pulp would have inherently made a hypo-allergenic pulp since the acidic solution, would have denatured the protein allergen as it reduced the bacteria load. Therefore, it would have been obvious to reduce the LTP in the process of the combined references.

Certainly sieving the juice to make the juice containing pulp into a juice which would have been suitable for microfiltration as the pulp in the juice would certainly clog the filter. Therefore, it would have been obvious to sieve juice in order to make it ready for microfiltration as in claim 2.

Claim 4 further requires that the sieved product has a solid percentage of from 1-20% and claim 5 that the solids are from 3-9%. However, removing a particular amount of pulp obtained from sieving or centrifugation is seen to have been within the skill of the ordinary worker according to how much pulp and juice were required. Therefore, it would have been obvious to make products containing particular amounts of pulp.

Claim 10 further requires particular amounts of pulp and serum. It would have been within the skill of the ordinary worker to use particular ranges because nothing new or unobvious flows from adjusting the juice or serum ranges.

Claims 11 and 12 further require particular ranges of ultrafiltration, and claim 13 requires particular amounts of retentate and permeates. Winterson et al. disclose that it is known to use

Art Unit: 1789

UF to separate juices using UF followed by microfiltration (MF) (page 4, lines 20-30).

However, it would have been within the skill of the ordinary worker to use particular ranges because nothing new or unobvious flows from adjusting the retentate or permeate ranges or using membranes with a particular cut off range.

Claim 28 further requires further homogenization, packaging and sterilization and claim 29 further requires freezing the product. All these processes are commonly used in making any fruit and vegetable product, since the product has to be mixed and packaged for the consumer, and can be further sterilized to make a shelf stable product. Therefore, it would have been obvious to use known processes to make a product ready for the consumer.

Claims 32 and 33 are to making a hypo-allergenic fruit or vegetable derivative, and claim 34 is to making the derivative into various products such as juice, and nectar etc.. These products basically depend on the ratio of puree to juice. As the process has been shown above, it would have been obvious to make the derivative into different products, which depend mainly on the ratio of puree to juice as shown by the combined references.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to claims 1- 5, 10-13, 28, 29, 32 and 33 above, and further in view of Le Rouzic (20050056161) and Desai et al. (5653673).

Claim 6 further requires a horizontal axis centrifuge of the decanter type. Le Rouzic discloses in a process of extracting juice and pulp from plant products, an apparatus with cylindrical strains, symmetrical about an axis in a tank with a perforated radial wall. A strainer with a horizontal axis of symmetry can also be used (0065). Also, Desai et al. disclose a solid-bowl centrifuge decanter, centrifugal apparatus for the continuous separating of solid (claim 8)

Art Unit: 1789

and liquid mixtures with an internal washing of the separated solids (paragraph under Background of the Invention). The references do not state whether they are horizontal or not, but in a method claim, if another apparatus can carry out the same function, the claimed one does not have to be shown. In addition, applicants' specification discloses that the claimed centrifuge may be used "or any other suitable to the purpose". Therefore, it would have been obvious to use a centrifuge of the decanter type to separate the solids from the liquid in the process of the combined references. .

Claim 7 requires within various speed ranges. The reference to Desai et al. disclose speeds up to 3300 rpm. (See Examples of the Invention, 1<sup>st</sup> paragraph under "general"). In treating fruits or vegetables it is well known that the flesh of the fruits or vegetables is subject to degradation under harsh speeds and temperatures. It would have been obvious to use particular speeds and temperatures in order to obtain an acceptable product.

The reference to Desai et al. teach a continuous configuration in a centrifuge apparatus as in claim 9 (abstract).

Claim 32 is to the product of the process of making a hypo-allergenic fruit or vegetable derivative.

The fact that the procedures of the reference are different than that of applicant is not a sufficient reason for allowing the product-by-process claims since the patentability of such claims is based upon the product formed and not the method by which it was produced. See *In re Thorpe* 227 USPQ 964. The burden is upon applicant to submit objective evidence to support their position as to the product-by-process claims. See *Ex parte Jungfer* 18 USPQ 2D 1796.

Art Unit: 1789

Therefore, it would have been obvious to make a hypoallergenic product as disclosed by the above combination of references.

Claims 14-17, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterson et al. (EP 0137671) or Lawhon et al. (EP 0174594) in view of Bishop as applied to claims 1-5, 10-13, 28, 29, 32 and 33 above, and further in view of Todorov et al. et al. (BG61472).

Claim 14 further requires concentration by reverse osmosis after UF. However, Todorov et al. disclose that it is known to ultrafiltrate juice, then to use reverse osmosis to concentrate the juice (abstract). It would have been within the skill of the ordinary worker to use reverse concentration in place of freeze concentration of Winterson et al. since both processes concentrate the juice absent a showing of anything unobvious or unexpected. Therefore, it would have been obvious to use reverse osmosis in place of freeze concentrating the juice of Winterson et al. since reverse osmosis also concentrates the juice.

Certainly, it would have been obvious to choose whatever type of reverse –osmosis membrane, which would make the required kind of juice as in claims 15 and 16, having a particular solids concentration as in claim 17, as this involves passing the juice through the membrane, and nothing new or unobvious results, but juice having a particular degree of clarity or solids.

Claims 25 and 26 further require that the pulp and permeate are mixed in a particular ratio and claim 27 particular solids are required. However, Todorov discloses that the juice and pulp were mixed to make a paste (abstract). Winterson et al. also disclose recombining the pulp and juice (abstract). Therefore, it would have been within the skill of the ordinary worker to



Art Unit: 1789

recombine the pulp and juice in various amounts and percent solids since it is known to produce both, and nothing unobvious arises from a simple combination of ingredients. It would have been obvious to recombine the products in particular amounts according to what end product was required.

Claims 19-20, 21-23, 24, 30, 31, 34, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterson et al. (EP 0137671) or Lawhon et al. (EP 0174594) in view of Bishop and Todorov et al. as applied to claims 1-5, 10-13, 28, 29, 32 and 33 above, and further in view of Loader (4,413,017) and Bishop (2,626,706).

Claim 19 further requires a .1 to 5% citric acid solution preferably 1% . However, it would have been within the skill of the ordinary worker to use enough acid for the function of preserving the pulp if no other treatment was to have been used for preservation. Therefore, it would have been obvious to use an acidic solution at within the claimed range to acidify the pulp as shown by Winterson et al. or Lawhon et al. in view of Radatti (20060159833) as applied to claims 1-5, 10-13, 28, 29, 32 and 33 above, and further in view of Loader (4,413,017) and Bishop (2,626,706).

Centrifugation as in claim 20 of the acidified pulp would have been obvious as disclosed above by the combined references. A second centrifugation step as in claims 20-23 would have been an obvious step in order to remove wash water from pulp since a pulp holding water would have added more liquid to the pulp and the product would not have been as concentrated.

Adding water during the second centrifugation as in claim 22 would have been within the skill of the ordinary worker. Nothing unobvious flows from the further step of continuous centrifugation during washing. One could wash the pulp in a separate apparatus then centrifuge

Art Unit: 1789

or do as claimed and nothing unobvious would have occurred, i. e. the pulp would have been washed.

The limitations of claims 21-23 have been disclosed above and are obvious for those reasons.

Claim 24 further requires that the washing step is repeated many times. Loader discloses that in commercial juice production, the pulp was washed to recover cold water soluble sugars. Certainly, this could have been comparable to washing as claimed until the pectin is removed. Applicants are removing allergens and the reference to Bishop was to removing pectin. However, the reference can be used for the teaching that it is known to wash pulp, and it would have been obvious to wash it enough to remove pectin or other unwanted substances such as allergens in the process of the combined references.

Claims 30 and claim 34 are to particular fruits and vegetables made into jams, puree and other products, and claim 35 is to tomato concentrate or juice, in particular. The composition of Loader uses fruits such as citrus, pineapple, and apple pulp (col. 4, lines 39-55). However, it would have been within the skill of the ordinary worker to use other fruits and vegetables as claimed, and no patentable distinction is seen in substituting different fruits or vegetables in the process of the combined references since they all contain juice and solids (pulp). Therefore, it would have been obvious to substitute other fruits and vegetables in the product made by the process of the combined references, for the citrus products of the combined references. .

Claim 31 is to using fresh tomatoes. However, tomatoes are a well known vegetable containing juice and pulp, and it would have been obvious to use tomatoes in place of the fruits or vegetables of the combined references which also contain juice and pulp.

### ARGUMENTS

Applicant's arguments filed 8-20-10 have been fully considered but they are not persuasive. Applicants argue that claims 33-35 are definite when read in light of the specification. This is not seen since the information from the specification has not been claimed. In addition, no ratio of pulp to permeate ratio is seen in the claims, in order to have made the jams or puree.

Applicants argue that the references are not combinable. However, they are seen to have been combinable for the reasons set forth above. In particular, it is argued that there was no reason to use an acid wash to obtain a hypoallergenic pulp when each of the references removes bacteria by other methods. However, using acid to remove bacteria at a pH of below 4.6 does not allow bacteria to grow either. If the acid wash is used, then it inherently removes proteins from the pulp. However, it is not seen that there are proteins in the pulp. Nothing in Applicants' specification says that washing with an acidic solution results in a hypo-allergenic pulp. Examples 1 and 2, only state that the end product will be stable over time (page 9, lines 4-8, and last 3 lines). Lawhon is not used alone, but in combination. Even if a deacidification step is used, the pulp was acid at one time, and this pulp combined with water would have made an acidified wash water. Applicants argue that the claims are to making a hypoallergenic fruit or vegetable derivative. Bishop discloses a method of extraction of pectin from sugar beet pulp. Even though the reference is to beet pulp and digesting the beet pulp in order to produce pectin, the reference still discloses that it is known to acidify vegetable pulp at a low pH. It would have been obvious to combine the references since the method shows washing a pulp with acid, which

Art Unit: 1789

would also have inherently reduced the microorganisms, just as applicants are by other methods.

No steps of using alcohol or precipitation of pectin are excluded from the claims.

It is not seen that Bishop is non-analogous art since it is to sugar beets, a fruit or vegetable, and even though the reference discloses extracting pectin from sugar beet waste material, this does not mean that bacteria are not also removed.

As to the 112 rejection, it is not seen that just adding pulp to a permeate will make a juice, nectar, etc. depending on the pulp to permeate ratio. As above, no ratio is claimed so that adding the permeate to the pulp would have resulted in a mixture of the two.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Keith Hendricks, can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Helen F. Pratt/  
Primary Examiner, Art Unit 1789

HP 10-8-10

/Keith D. Hendricks/

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